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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,627	08/19/2003	Johan Sundelin	MPI93-006CP1DV1ACN1DV1M	4455

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EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,627	SUNDELIN ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27,28,30,32,34-41 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,28,34-41,44 and 45* is/are rejected.

7)☒ Claim(s) *30,32,46 and 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 10/127,691, 08/474,414, 08/390,301 and 08/097,938, filed 4/23/02, 6/7/95, 1/25/95 and 7/26/93, respectively. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This

time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. It is noted that applicants claim priority in the Transmittal Letter filed 8/19/03 and hence a petition is not required in this case.

Election/Restriction

Applicant's election with traverse of Group IV in the reply filed on 1/18/05 is acknowledged. The traversal is on the ground(s) that the examiner has ignored unifying features of the sequences. Applicants argue that the sequences should be grouped according to animal species and that the C140 sequences from humans (SEQ ID NO:s 3-4, 62-63, Groups II and IV) should be examined together. Likewise applicants

indicate that Groups I and III, reading on murine C140 sequences, should be merged. Applicants assert that a search of the human sequences together would not be burdensome because they are closely related in sequence. Applicants' arguments regarding merging groups II and IV as well as Groups I and III are persuasive. Applicants' election of Groups II and IV is acknowledged. The merger of Groups I and III is however, moot given applicants' cancellation of all non-elected subject matter.

The requirement is still deemed proper and is therefore made FINAL.

35 USC 112, 1st Paragraph Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-28, 34-41 and 44-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim an isolated C140 receptor polypeptide encoded by a nucleic acid which hybridizes under stringent conditions to a nucleic acid molecule complimentary to SEQ ID NO:3 or SEQ ID NO:62 wherein the polypeptide comprises at least about 75% or 95% amino acid sequence identity with either SEQ ID NO:4 or 63 or is an agonist or antagonist of C140 receptor induced Ca^{2+} release wherein the agonist

or antagonist is at least 75%, 90% or 95% identical to the N-terminal end of the activated C140 receptor. Applicants disclose the human C140 cDNA and genomic sequences (SEQ ID NO:3, 62) and the polypeptide sequences of human C140 (SEQ ID NO:4, 63), peptide agonists and antagonists of human C140 wherein said agonists and antagonists are C140 peptides as well as murine C140 DNA and polypeptide sequences. The instant claims read on a genus of isolated polypeptide sequences encoding any C140 receptor polypeptide. Applicants define the scope of polypeptides encompassed within the definition of "C140 receptor polypeptides" on page 13 of the specification as follows:

> C140 receptor polypeptides include those containing predetermined mutations by, e.g., homologous recombination, site-directed or PCR mutagenesis, and Cl40 receptor polypeptides of other animal species, including but not limited to rabbit, rat, murine, porcine, bovine, ovine, equine and non-human primate species, and alleles or other naturally occurring variants of the C140 receptor of the foregoing species and of human sequences; derivatives of the commonly known C140 receptor or its fragments wherein the C140 receptor or its fragments have been covalently modified by substitution, chemical, enzymatic, or other appropriate means with a moiety other than a naturally occurring amino acid (for example a detectable moiety such as an enzyme or radioisotope); glycosylation variants of Cl40 receptor (insertion of a glycosylation site or deletion of any glycosylation site by deletion, insertion or substitution of appropriate amino acid); and soluble forms of C140.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed

invention. In the present case, applicants have not presented a correlation between the structure of the claimed C140 receptor molecules and the function of those molecules as C140 receptors. For example, applicants claim C140 receptor polypeptides from other animal species and with the exception of mice, applicants have not disclosed the structure of any other C140 receptor polypeptides. Applicants have disclosed no variants of the human or mouse C140 receptor polypeptides. While applicants have characterized the human (and murine) C140 receptor molecule with regard to it's being a member of the large and diverse G protein coupled receptor family (i.e. having seven transmembrane regions common to said proteins) as well as having **potential** asparagine linked glycosylation sites and a **putative** protease receptor cleavage site at Arg34-Ser35, applicants have not disclosed the regions of the molecule which would be conserved and are essential for activity. It is noted that the art is replete with examples of numerous other G protein coupled receptors which have seven transmembrane regions and putative protease cleavage sites (See for example, Shi et al., Mol. Cancer Res., 2004, Vol. 2(7), pp. 395-402). Without elucidation of the sequences which are essential for a protein to be recognized as a C140 receptor polypeptide, the skilled artisan would not be able to recognize whether any given polypeptide containing a putative protease receptor cleavage site and seven transmembrane regions characteristic of hundreds of different G protein coupled receptors and protease activated receptors would or would not be a C140 receptor specific polypeptide. With regard to agonists and antagonists of C140 receptor induced Ca^{2+} release, given the absence of a disclosure of the structures of other C140 receptor polypeptides, the

nature of the cleavage sites in said polypeptides, the enzymes involved in cleavage, the sequences which could be functional as agonists or antagonists of C140 receptor activity, etc., it must be considered that the skilled artisan would not conclude that applicants were in possession of the claimed agonists and antagonists. Indeed, Shi et al. (cited above) recites several different (closely related) protease-activated receptor (PAR) proteins which are similar to the instant C140 polypeptide and notes that agonists against one PAR would not be active against proteins encoded by other members of the same gene family. It must be considered, absent evidence to the contrary, that the two C140 sequences disclosed by applicants as well as the disclosed agonists and antagonists of human C140 receptor polypeptides are not a representative number of species sufficient to provide a description of the claimed genus. The skilled artisan would therefore not conclude that applicants were in possession of the claimed genus.

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27 and 36-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,763,575 (hereafter the '575 patent). Although the claims are not identical, they are not patentably distinct from each other because both sets of claims recite agonists and antagonists of C140 receptor activity. The instant claims are generic, encompassing any agonists or antagonists of C140 activity and are generic to all that is claimed in the '575 patent. That is claims 1-11 of the '575 patent fall entirely within the scope of claims 27 and 36-40 of the instant application, or in other words, claims 27 and 36-40 are anticipated by the claims in the '575 patent. Specifically, the agonist peptide of claim 1 in the '575 patent reads on, for example, the polypeptide Ser-Leu-Ile-Gly-Lys-Val, which is an isolated C140 receptor polypeptide which can be encoded by a nucleic acid sequence which is identical (and hence hybridizes to) a nucleic acid complementary to SEQ ID NO:62. The agonist or antagonist peptides, either the specific peptides recited in claims 4 or 11, or the peptides encompassed by the formulae recited in the remaining claims in the '575 patent are likewise encompassed within the generic instant claims reading on agonist or antagonist peptides. It is noted that the N-terminal end of the activated C140 receptor is believed by applicants to be the sequence Ser-Leu-Ile-Gly-Lys-Val... after cleavage by protease. With regard to agonists or antagonists of C140 receptor induced Ca^{2+} release recited in the instant claims, it is noted that the activity of compounds which activate or inhibit the C140 receptor is measured by Ca^{2+} mobilization and hence measurement of activation or

inhibition of the C140 receptor by agonists or antagonists can be done by measuring C140 receptor induced Ca^{2+} release.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 27 is rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Polita et al.

Applicants claim an isolated C140 receptor polypeptide encoded by a nucleic acid molecule which hybridizes under stringent conditions to a nucleic acid molecule complimentary to SEQ ID NO:3 or 62. No size limit is recited for the C140 polypeptide and hence the claim reads on any C140 sequence (e.g. two or three amino acids) which can be encoded by the recited nucleic acid molecules.

Polita et al. (US 5,143,903, issued 9/1/1993, filed 9/14/1990, see whole document, particularly column 1, lines 1-25; Claims 1-6) recites isolated peptide compounds and their use as therapeutic compounds. The compounds include, for example, the tripeptide Pro-Leu-Tyr which is a C140 polypeptide (see residues 209-211

of SEQ ID NO:4, encoded by SEQ ID NO:3). Polita et al. therefore teaches the claimed invention.

Miscellaneous

Applicants indicate that an Information Disclosure Statement (IDS) was filed 8/19/03; however, no IDS is of record in the file.

No Claims are allowed.

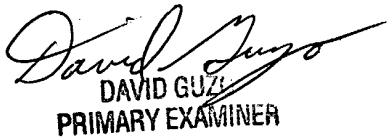
Claims 30, 32, 46 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
March 30, 2005



DAVID GUZO
PRIMARY EXAMINER